

EXPLANATORY MEMORANDUM TO
THE NATIONAL HEALTH SERVICE COMMISSIONING BOARD AND
CLINICAL COMMISSIONING GROUPS (RESPONSIBILITIES AND
STANDING RULES) (AMENDMENT) (No. 2) REGULATIONS 2014

2014 No. 452

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.
2. **Purpose of the instrument**
 - 2.1 These Regulations amend The National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 (“the principal Regulations”). Amongst other things, the principal Regulations prescribe the health services for people with rare and very rare conditions which the NHS Commissioning Board (“the Board”) must commission under section 3B of The National Health Service Act 2006 (“the 2006 Act”), as amended, in particular by the Health and Social Care Act 2012. They also require the Board to commission health services for persons detained in prescribed secure accommodation.
3. **Matters of special interest to the Joint Committee on Statutory Instruments**
 - 3.1 None.
4. **Legislative Context**
 - 4.1 Section 3B of the 2006 Act enables regulations to be made by the Secretary of State requiring the Board to arrange for the provision of certain services. These are services in addition to those that the Board will be responsible for commissioning under section 4 and Parts 4 to 7 of the 2006 Act. The regulations may require the Board to arrange for the provision of certain dental services (section 3B(1)(a)), health services for members of the armed forces and their families (section 3B(1)(b)), and health services for people detained in prisons or other accommodation of a prescribed description (section 3B(1)(c)). Under section 3B(1)(d) and subsection (2), regulations may also prescribe certain other services or facilities which the Board must commission, subject to the Secretary of State considering it is appropriate for the Board to have commissioning responsibility (rather than CCGs), and having regard to certain specified factors set out in section 3B(3) (as to which factors, see paragraph 7.2). The National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 specify those services that the Board should commission.

4.2 Under regulation 10 of and Schedule 3 to the principal Regulations, the Board commissions health services in prisons and certain other prescribed secure accommodation, including secure children's homes. Exceptions to this are set out in Part 1 of Schedule 3 to the principal Regulations. These Regulations will amend regulation 10 and Schedule 3 to remove those exceptions.

4.3 Schedule 4 to the principal Regulations sets out those health services for persons with rare and very rare conditions which the Board must commission pursuant to regulations 7, 10 and 11 of the principal Regulations. These Regulations update Schedule 4 by inserting two new specialist services.

4.4 Prior to making regulations under section 3B of the 2006 Act, the Secretary of State must obtain appropriate advice and must consult the Board, as required under subsection (4) of that section. The Secretary of State has consulted with the Board and has also obtained advice as to the desirability of ensuring that the Board should have commissioning responsibilities as provided for in these Regulations (more detail is set out under "Policy background" and in paragraph 8.2). In light of that consultation and advice, and, in respect of Schedule 4 amendments, having regard to the factors prescribed in section 3B(3), the Secretary of State has decided to make these amending Regulations.

4.5 Making these Regulations is consistent with the Secretary of State's general duties under Part 1 of the National Health Service Act 2006. The amendments aim to ensure consistent quality of care and access to NHS services for small groups of patients with rare and very rare conditions, on the basis that national commissioning will achieve more focussed provision, using selected providers and enabling access to experts, thereby affording highly specialist care to those who need it.

4.6 The amendments also aim to improve the health and wellbeing outcomes of vulnerable children and young people in welfare-only accommodation in secure children's homes whilst they are in the secure setting. It is thought that bringing such vulnerable children and young persons into the single commissioning model across the whole of the secure estate in England will help assure them the same quality of care that other children in secure accommodation receive, and will better maintain continuity of care when they are released.

4.7 The policies these amendments give effect to are therefore consistent with the Secretary of State's duties in relation to quality improvement and inequalities in that they aim to improve quality of care for small groups of patients with very particular, sometimes complex needs and issues, the rareness of whose conditions or whose individual circumstances might otherwise disadvantage them in terms of health outcomes or access to services. The policy upholds the NHS Constitution principle that "everyone counts". With regard to the Secretary of State's duty in relation to autonomy, the Secretary of State has taken advice from and consulted the Board before making these changes under section 3B, and where services are required to be

commissioned by the Board in accordance with the amendments in these Regulations, it has autonomy to determine how these services are commissioned and delivered. The amendments do not directly provide an opportunity to promote research but the data collected by the Board through national commissioning of these services may support future research.

5. Territorial Extent and Application

5.1 This instrument applies to England only.

6. European Convention on Human Rights

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 Although most services in the NHS other than primary care are commissioned by CCGs, there are different arrangements for commissioning some services including those for people with rare and very rare conditions where the services are often high cost and where expertise needs to be concentrated. In these cases, the Board has responsibility for commissioning them. The obligation on the Board set out in the principal Regulations is, in terms, that it must arrange to such extent as it considers necessary to meet all reasonable requirements for the provision of the specified services as part of the health service. A group of clinical experts and lay persons, known as the Prescribed Specialised Services Advisory Group (PSSAG), was established by the Secretary of State to provide advice to Ministers on which services are specialised and should be commissioned nationally by the Board for persons with rare and very rare conditions.

7.2 On 31st December 2013, and after having received advice from PSSAG, the Secretary of State for Health commenced formal consultation with the NHS Commissioning Board on the changes PSSAG had recommended to the portfolio of services contained within Schedule 4 to principal Regulations. The recommended changes are:

- i. To add a new service for atypical haemolytic uraemic syndrome
- ii. To add a new service for hand transplantation for adults

7.3 Further detail on these services can be found in the table at the Annex to this Memorandum. These Regulations will provide for those two additional specialist services to be included within the national arrangements for commissioning specialised services, which the Secretary of State, having obtained PSSAG's advice, considers appropriate, having regard to the four factors set out in section 3B of the 2006 Act. These are:

1. The number of individuals requiring the provision of the service or facility;
2. The cost of providing the service or facility;
3. The number of persons able to provide the service or facility; and
4. The financial implications for CCGs if they were required to arrange for the provision of the service or facility.

7.4 In relation to the amendments concerning secure children's homes, the policy intention following the health service reforms introduced by the Health and Social Care Act 2012 is for the Board to have responsibility for commissioning health services for prisoners and other detainees in prison or other secure accommodation.

7.5 Under the principal Regulations, the Board currently has responsibility for commissioning health services across all secure accommodation but there are two exceptions: secure training centres (although that exception only applies until 1st April 2014) and secure children's homes with what are referred to as "welfare only beds". This term refers to secure accommodation which provides specialised support for young people between the ages of 10-17 years who are particularly vulnerable and considered to be a risk to themselves or others, rather than as part of the criminal justice system. The following secure children's homes providing "welfare only" accommodation are currently excepted from the requirement for the Board to commission health services: Atkinson; Beechfield; Kyoel House; Lansdowne; Clare Lodge; Leverton, and St Catherines. These homes currently comprise 79 beds in total.

7.6 These secure children's homes with welfare only beds are currently the responsibility of the local authority in whose areas they are located. Health care provision is arranged according to local health needs assessments. They were excluded from the principal Regulations when those Regulations were first made because of the complexities in disaggregating the funding from Local Authorities and transferring it to NHS England in time for April 2013. These issues have now been addressed.

7.7 These Regulations will therefore bring such homes into the Board's commissioning responsibility, giving effect to the policy intention described above and ensuring that across England the group of vulnerable children occupying welfare only accommodation will have the benefit of Board commissioned NHS care. Having one model of commissioning for health services across the whole of the secure estate will deliver improved patient experience and assurances that the most vulnerable children and young people will receive the same quality of care and access to services as other young people in the secure estate and in the community.

7.8 In making the amendments relating to secure children's homes, the Secretary of State has had advice from the Board and from the Project Board established by the Department of Health (described in paragraph 8.2 in more detail).

8. Consultation outcome

8.1 In respect of the amendments to Schedule 4 concerning specialist services, in accordance with the Secretary of State's powers under section 3B of the 2006 Act, the Secretary of State has sought appropriate advice as described above from the Prescribed Specialised Services Advisory Group, which is an independent stakeholder advisory group, established by the Department to advise Ministers on specialised services for persons with rare and very conditions. PSSAG includes experts and lay members representing patient interests.

8.2 The Secretary of State also sought appropriate advice in relation to the amendments concerning secure children's homes. The Project Board established by the Department of Health to oversee the transfer of commissioning responsibility for secure children's homes and secure training centres included a wide range of stakeholders including the Youth Justice Board, Department for Education and representatives from the sites themselves, as well as the NHS Commissioning Board itself. Before deciding whether to make amendments to the regulations in this respect, the Secretary of State has taken into account their comments.

8.3 In respect of all the amendments in these Regulations, before deciding whether to make these Regulations, the Secretary of State has also consulted the Board and has taken into account its comments.

9. Guidance

9.1 The Board will notify CCGs and affected local authorities, as well as any relevant providers of services, of the new commissioning arrangements. The Board will also be able to issue information on its commissioning of health services in secure accommodation.

10. Impact

10.1 The impact on business, charities or voluntary bodies is negligible.

10.2 In respect of the amendments relating to specialised services, the impact on the public sector is specific only to providers of specialised services at NHS Trusts and NHS Foundation Trusts. The impact on the Board as the commissioners of the additional specialist services is to increase marginally the range of services for which it has commissioning responsibility. In respect of the amendments relating to the secure children's homes, the impact on the public sector is considered negligible. The overall impact of these amendments in terms of NHS commissioning is neutral.

10.3 An impact assessment has not been prepared for this instrument. In terms of commissioning generally, an Impact Assessment was prepared in relation to the Health and Social Care Bill 2012 which considered costs and costs savings of what is now the current commissioning model, at Annex A (pages 3-29) (to be found at

www.dh.gov.uk/prod_consum_dh/group/dh_digitalassets/documents/digitalasset/dh_129917.pdf).

11. Regulating small business

11.1 The legislation does not apply to small business.

12. Monitoring & review

12.1 The Secretary of State remains accountable for keeping the NHS Commissioning Board's performance under review in line with his duty under the National Health Service Act 2006. The Regulations will be reviewed annually and updated as required.

13. Contact

In relation to amendments concerning specialist services, contact Sarah Bramley-Harker at the Department of Health, Tel: 0113 2546708 or email: sarah.bramley-harker@dh.gsi.gov.uk, who can answer any queries regarding the instrument. In relation to the amendments concerning secure children's homes, contact Angela Hawley at the Department of Health, telephone 0113 254 6577, or email angela.hawley@dh.gsi.gov.uk .

New Service	Description
Atypical haemolytic uraemic syndrome services	<p>Atypical haemolytic uraemic syndrome (aHUS) is a rare condition that results in clots (thrombotic) in the small (micro) blood vessels (angiopathy). This thrombotic microangiopathy affects the brain, gut, kidneys and other organs.</p> <p>Number of individuals requiring the provision of the service or facility: the number of individuals requiring the service is very small - there are about 140 known patients in England, with an estimated prevalence of up to 286.</p> <p>Cost of providing the service or facility: the cost of providing the service to an individual is very high because of the drug costs involved.</p> <p>Number of persons able to provide the service or facility: the number of centres with the expertise to provide the service is extremely small.</p> <p>Financial implications for Clinical Commissioning Groups if they were required to arrange for the provision of the service or facility: there would be a significant financial impact on some individual CCGs if they were to commission this service.</p>
Hand transplantation for adults	<p>Hand transplantation is a surgical procedure to attach the hand of one human being to another. The surgery involved is extremely complex and recipients have, as with other cadaveric transplants, to take immunosuppressive drugs for life to prevent the transplanted organ being rejected.</p> <p>Number of individuals requiring the provision of the service or facility: the number of individuals requiring the service is extremely small; as of March 2011, only 52 patients worldwide had received a total of 70 hands.</p>

	<p>Cost of providing the service or facility: the cost of providing the service is very high because of the very complex surgery involved and the associated care.</p> <p>Number of persons able to provide the service or facility: the number of centres with the expertise to provide the service is extremely small; only one centre in the UK has undertaken a hand transplant to date.</p> <p>Financial implications for Clinical Commissioning Groups if they were required to arrange for the provision of the service or facility: there could be a significant impact on individual CCGs if they were to commission this service.</p>
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